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EXAMINER	
SMITH, PHILIP ROBERT	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,771	BALA, JOHN L.	
	Examiner	Art Unit	
	Philip R. Smith	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/4/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112, Paragraph One

[01] The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[02] Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

[03] The specified "laser effects (i.e. ring-mode applicators, convergent beams, divergent beams, and scattering applicators) that will create different patterns of laser photothermal ablation or photocoagutatlon" appear to be rendered ineffectual by the fiber conduit and optical probe.

[04] Applicant specifies in [0045] that "the bifurcated fiber optic conduit 74 multiplexes or randomizes the non-coherent light output of the fourth flashtube assembly 82 and the coherent light output of the laser unit 68 to produce a single light output to the conduit segment 32 of the second service cable assembly 30." Furthermore, Applicant states that the "optical probe 88 is tubular." It is not reasonably conveyed how the particular patterns projected onto the input end of a fiber optic,

once randomized, multiplexed, and made to conform to an annular probe tip, would have any coherent effect upon illumination of the target area. Conventionally, an optical connector positioned between a laser light source and a fiber optic cable has convergent characteristics, exemplified by a Gaussian mode and a ring-mode. A divergent or scattering characteristic, as conventionally understood by a skilled artisan, is necessarily applied to illumination light between the fiber optic cable and the target area; scattering and divergence at the input of the fiber optic cable would result in nothing more than inefficient transmission of power. Convergence, whether characterized by Gaussian or ring-like distribution, is conventionally used to maximize power transfer from a light source to a fiber optic cable, and is effectively accomplished with condensing lenses.

Claim Rejections - 35 U.S.C. 112, Paragraph Two

[05] The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[06] Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[07] *With regard to claim 19:* It is not clear how a target can be painted on a video monitor, given the claimed structures. Other claims refer to a "target area" to which light is directed.

Claim Rejections - 35 USC § 102

[09] The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[10] Claims 1-2 & 22 rejected under 35 U.S.C. 102(b) as being anticipated by Imaizumi (6,293,911), patented 25 September 2001.

[11] *With regard to claims 1 & 22:* Imaizumi discloses an endoscope system for providing imaging and intervention therapy comprising:

[11a] a light source ("light source apparatus 3C," column15/ line57) in electrical communication with a control module;

[11b] an intervention energy source ("laser light source 7," column7/ lines34-38) in electrical communication with a control module;

[11c] a second service cable assembly electrically and optically connecting the light source (via "light guide fiber 9," 5/51-57) and the intervention energy source (via "laser guide 35," 7/34-38) to a micro-endoscopic device;

[11d] the micro-endoscopic device ("electronic endoscope 2C," 15/50-63) including a sensor array ("CCD 39," 17/9-15) in electrical communication with the control module, an optical probe ("distal part 15," 6/14-23) in optical communication with the second service cable assembly and the sensor

array, and an object lens ("objective lens 18," 6/14-23) in optical communication with the optical probe;

[11e] wherein the light source is activated by the control module to emit a series of light pulses (resulting from "lamp 11" and "RGB filter 41," 16/18-27), the second service cable assembly conducts the light pulses to the optical probe (via "light guide fiber 9," 5/51-57), the optical probe directs the light pulses to a target area ("living tissue 17 in a body cavity through an illumination lens 16 attached to an illumination window," 6/3-13), the object lens collects light reflected from the target area (6/16-19), the optical probe conducts the reflected light to the sensor array (17/10-13), and the sensor array transmits (via "signal cable 38," 17/19-22) an image of the target area to the control module (comprising "processor 5B," 15/55-57).

[11f] The "laser light source 7" disclosed by Imaizumi inherently has some activation interface through which it is operable to emit intervention energy. The activation interface further composes the claimed control module.

[11g] As shown in Fig. 14, the "processor 5B" disclosed by Imaizumi (which composes the control module) is electrically connected to the light source. The above-mentioned activation interface (which composes the control module) is electrically connected to the intervention energy source. These two electrical connections compose the claimed first service cable assembly.

[12] *With regard to claim 2:* Imaizumi discloses the following, which may further compose a control module:

[12a] a video monitor ("monitor 6," 7/26);

[12b] system power supplies (an inherent requirement of any electrical system);

[12c] system processing and control electronics unit ("processor 5B").

Additional Claim Rejections - 35 USC § 102

[13] Claims 1-3 & 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Sendai (6,468,204), patented 22 October 2002.

[14] *With regard to claims 1 & 22:* Sendai discloses an endoscope system for providing imaging and intervention therapy comprising:

[14a] a light source ("illuminating unit 110" comprising "white light source 114," 18/17-32) and intervention energy source ("semiconductor laser 111," 18/17-32), both in electrical communication with a control module via a first service cable assembly;

[14b] a second service cable assembly electrically and optically connecting the light source (via "composite glass fiber white light guide 101a," 17/63-18/15) and the intervention energy source (via "stimulating light guide 101b," 17/63-18/15) to a micro-endoscopic device;

[14c] the micro-endoscopic device ("endoscope insertion portion 100," 17/63-18/15) including a sensor array (comprising "normal-image detecting

element 107," 17/63-18/15 and "fluorescent-image use high sensitivity detecting element 316," 35/38) in electrical communication with the control module, an optical probe ("forward end portion of endoscope insertion portion 100") in optical communication with the second service cable assembly and the sensor array, and an object lens ("focusing lens 106" & "focusing lens 105," 17/23-62) in optical communication with the optical probe;

[14d] a control module (comprising "computer 200," "image detecting unit 300," "image computing unit 400" & "display signal processing unit 500," 17/23-62).

[14e] wherein the light source is activated by a control module to emit a series of light pulses, the second service cable assembly conducts the light pulses to the optical probe (via "101a"), the optical probe directs the light pulses to a target area, the object lens collects light reflected from the target area, the optical probe conducts the reflected light to the sensor array, and the sensor array transmits an image of the target area to the control module (comprising "display signal processing unit 500").

[15] *With regard to claims 2-3:* Sendai further discloses the following, which may further compose a control module:

[15a] a video monitor ("monitor 600," 17/28);

[15b] system power supplies (an inherent requirement of any electrical system);

[15c] system processing and control electronics unit (comprising "computer 200," "image detecting unit 300," "image computing unit 400" & "display signal processing unit 500," 17/23-62) comprising a memory and software stored in the memory (an inherent requirement of any computer), the software controlling the video monitor, the system power supplies, the intervention energy source and the micro-endoscopic device (17/23-62).

Claim Rejections - 35 USC § 103

[16] The text of those sections of Title 35, U.S. Code The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[17] Claims 4-8, 12-16 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sendai in view of Moore et al. (4,253,447, Re. 31,289), reissued 28 June 1983, and in further view of Bala (6,679,838), published 31 January 2002.

[18] *With regard to claims 4-6 & 21:* Sendai discloses the entirety of claim 1, upon which claims 4-6 depend. Sendai further discloses the entireties of claims 2-3, which are partially replicated in claim 21. Sendai does not disclose the following:

[18a] first, second, and third xenon flashtube assemblies which compose the light source, each of the flashtube assemblies activated by the control electronics unit to emit light and a band-pass filter passing a narrow frequency band of the light emitted by the flashtube, the band-pass filters of the first, second and third flashtube assemblies passing red, green & blue respectively, with a light focus optic disposed intermediate the color separation filters and the second service cable assembly.

[19] Moore discloses an endoscope system for providing imaging and intervention

therapy comprising

[19a] first, second, and third flashtube assemblies ("three individual strobe lamps 13-15," 2/48-49) which compose a light source ("light handling section 12," 2/47-48), each of the flashtube assemblies activated by a control electronics unit ("by means of a strobe drive 17," 2/47-50) to emit light filtered to pass red, green & blue respectively ("red, green, and blue sequence," 2/65), with a light focus optic ("optical elements 18-20," 2/51) disposed intermediate the color separation filters and the second service cable assembly, allowing for sequential control of the flashtube assemblies.

[20] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the "white light source 114" disclosed by Sendai be replaced with the "light handling section 12" disclosed by Moore such that Sendai's invention is made "capable of producing a readout signal containing full color image information that is compatible with standard format television" (Moore's abstract). Sequential illumination of RGB light is a well-known alternative to continuous white illumination; it better allows for NTSC compatibility, a feature that is clearly advantageous to a skilled artisan.

[21] Sendai in view of Moore does not disclose that the plurality of flashtube assemblies each comprise a xenon flashtube. Bala discloses that a "conventional optical probe will incorporate conventional fiber optic light transmission and image collection pathways. Increased light intensity provided by the pulsed xenon light source permits the use of fewer fibers for light transmission, freeing more probe

fibers for image collection." At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the flashtube assemblies disclosed by Moore be, in reduction to practice, constituted by xenon flashtube assemblies for the reasons stated above by Bala.

[22] *With regard to claims 7-8:* As noted above, Sendai discloses a second service cable assembly having a conduit segment and an input segment ("composite glass fiber white light guide 101a"). Sendai does not disclose that the input segment is a trifurcated fiber optic conduit having three input ends and a single light output to the conduit segment, a one of the input ends being in optical communication with each of the flashtube assemblies. Moore further discloses the following in 2/67-3/8:

> As seen in FIG. 3, the proximal end of the fiber bundle 22 is trifurcated with each arm being positioned adjacent to one of the optical elements 18-20. The light entrance face of each arm is generally perpendicular to the optical centerline of the adjacent element and lies about within the focal place of the element. Accordingly, a preponderance of the light passing through each element is caused to enter the bundle and is channeled along the flexible bundle into the remote viewing head 11.

[23] For the reasons stated above, it would have been obvious to a skilled artisan that the "white light source 114" disclosed by Sendai be replaced with the "light handling section 12" disclosed by Moore such that Sendai's invention is made "capable of producing a readout signal containing full color image information that is compatible with standard format television." A trifurcated input segment, presented clearly in Fig. 3, is necessary for the integration of Moore's invention into Sendai's; this is clear to a person of ordinary skill, and easily accomplished.

[24] *With regard to claims 12-13:* Sendai in view of Moore, and in further view of Bala discloses the entirety of claim 5, as noted above. The combination of Sendai and Moore results in a trifurcated input segment for RGB light ("fiber bundle 22") and an input segment for intervention energy ("stimulating light guide 101b"), each with a corresponding conduit segment. The summation of these segments results in a quadrifurcated fiber optic input segment having first, second, third and fourth input ends, the first, second and third input ends ("fiber bundle 22") being in optical communication with the first, second and third flashtube assemblies, respectively, and the fourth input end ("stimulating light guide 101b") being in optical communication with the intervention energy source. The intervention energy source disclosed by Sendai is a therapeutic laser unit ("GaN type semiconductor laser 111 for emitting fluorescent-image use stimulating light Lr, which has a wavelength of 410 nm," 18/22-23).

[25] *With regard to claims 14-16:* Sendai discloses a mechanical fail-safe shutter ("stimulating light cutoff means 724... for putting the stimulating light in the emission-prohibited state," 36/10-36) disposed between the laser unit and the fourth input end, the shutter being in electrical communication with the control module (further comprising "stimulating light emission prevention control portion 727"), whereby the control module maintains the shutter in a closed position except when intervention therapy is administered (as signaled by the "power-source state detecting portion 721"). Sendai further discloses a shutter ("optical transmitting filter 313," 35/32) in electrical communication with the control module

(via "filter rotating apparatus 314," 35/34), the shutter being disabled in a closed position when intervention therapy is administered (...313a transmits light in the wavelength range of 430 nm to 730 nm, and optical filter 303b transmits light in the wavelength range of 430 nm to 530 nm," 35/44-48), allowing for sequential control of the laser unit.

Additional Claim Rejections - 35 USC § 103

[26] Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sendai in view of Fort (5,278,639) patented 11 January 1994.

[27] Sendai discloses the entirety of claim 1, including a second service cable assembly including an optical conduit including a fiber optic bundle defining a light path and an electrical conduit; and a micro-endoscopic device including an optical probe and a sensor array.

[28] Sendai further discloses that the light source emits ultraviolet light ("stimulating light Lr, which has a wavelength of 410 nm," 19/45-55) and the optical conduit also includes an ultra violet filter ("stimulating light cutoff means 724," 36/16), the ultraviolet filter being movable from an imaging position, within the light path ("emission-prohibited state"), to a intervention position ("unlocking the emission-prohibited state"), outside of the light path (36/47-54).

[29] Sendai further discloses a UV filter ("stimulating light cutoff filter 312," 35/28) disposed between the optical probe and the sensor array.

[30] Sendai does not disclose that the second service cable assembly comprises an

infrared filter disposed within the light path.

[31] Fort discloses the following in 3/51-56:

> An anti-heat device 20 follows the lamp 10. This device includes two anti-heat filters 21 and 22 which are spaced apart in appropriate manner and which serve to provide the necessary thermal protection by eliminating the infrared radiation (IR) in the light emitted by the lamp 10.

[32] It is well-known in endoscopy, or any imaging art, that infrared wavelengths result in unwanted image information that does not relate to the visible spectrum. For this reason, light sources are commonly equipped with infrared cut filters. At the time of the invention, it would have been obvious to a person of ordinary skill in the art that Sendai be modified to include a filter which removes infrared components from the light source in order to thermally protect the endoscope.

Additional Claim Rejections - 35 USC § 103

[33] Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sendai in view of Moore and Bala, and in further view of Neuberger (6,485,414), patented 26 November 2002.

[34] As noted above, Sendai in view of Moore and Bala disclose the endoscope system of claim 4 wherein the light source comprises first, second, third flashtube assemblies (RGB respectively). Further disclosed is a second service cable assembly comprising a conduit segment and an input segment including a trifurcated fiber optic conduit having first, second and third input ends in optical communication with the first, second and third flashtube assemblies, respectively. Further disclosed is a video monitor, system power supplies, and a system

processing and control electronics unit. Further disclosed is that the intervention energy source is a therapeutic laser unit, and a fifth input end in optical communication with the intervention energy source. Further disclosed, in the rejection of claim 14, is an optical connector comprising turret-mounted optics providing selection of different laser effects.

[35] Sendai in view of Moore and Bala does not disclose a fourth flashtube assemblies wherein the color separation filter of the fourth flashtube assembly is in the visible range of the color spectrum. Nor a fourth input end being in optical communication with the fourth flashtube assembly. Nor a bifurcated fiber optic conduit comprising the fourth and fifth input ends. Nor that the system processing and control electronics unit that activates the fourth flashtube assembly to paint the target area onto the video monitor.

[36] Neuberger discloses a color video diagnostic system. Just as with the system disclosed by Sendai in view of Moore and Bala, Neuberger discloses sequential illumination of a target area with red, green, and blue light. In addition to red, green, and blue light, Neuberger includes in this sequence an additional light source which he refers to diagnostic. Neuberger discloses the following in 3/16-37:

> ... A black-and-white video chip mounted at the distal end of an endoscope body images an object sequentially illuminated by laser diode light sources having different wavelengths ... A controller controls the laser diode light sources for sequentially illuminating the object by color, and a video processor responsive to the controller receives signals from the black-and-white video chip for producing a color data signal. A display displays a color image of the object. At least one diagnostic laser diode light source, which can be tunable, may be included for enhancing selected features of the object being viewed, and it may emit in the visible, near infrared, or infrared wavelength regions. A beam-combining

> element can be included for combining the light beams from the laser diode light sources for provision to a fiber light transport element for transporting the light to illuminate the object.

[37] Neuberger teaches that it is advantageous to include an additional light source (beside the conventional RGB) for specific diagnostic purposes. The following is disclosed particularly in 3/5-15:

> It is another object of the present invention to include a diagnostic laser diode light source having a wavelength selected for fluorescing an imaging agent for imaging a selected feature of an object being viewed. The object is exposed to an imaging agent, which is selected to target a specific feature of the object and which is known to be excited by a predetermined wavelength of light to fluoresce. The diagnostic laser diode light source is selected to operate at the predetermined wavelength, which may be within the near infrared spectral region. The feature, if part of the object, can be more readily distinguished on the video display of the color signal.

[38] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that an additional light source be utilized in addition to the RGB xenon flashtubes disclosed by Sendai in view of Moore and Bala. A fourth flashtube assembly would be added in order to paint a target area ("target a specific feature of the object ... which is known to be excited by a predetermined wavelength of light to fluoresce"). The would obviously require a color separation filter corresponding to the "predetermined wavelength."

Conclusion

[39] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Doguchi (20047/0143157) discloses sequential illumination of a medical target using RGB LEDs. Farkas (2004/0230098) discloses illumination of a target with white light and a therapeutic laser. Fulghum (2002/0161282) discloses laser use in an autofluorescence endoscope.

Hakamata (2002/0038074) discloses an endoscope with a therapeutic laser.

[40] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.

[41] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.

[42] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

prs

John P. Leubecker
Primary Examiner